Form PTC

Form PTO-1449 (modified)

cLFR:115USC1
Applicant

Serial No. 10/801,277

st of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Staley A. Brod

March 16, 2004

Atty. Docket No.

Filing Date:

Group:

1647

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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
/JS/	A1	4,409,243	10/11/83	Lieb	424	330	11/9/81
1	A2	4,462,985	7/31/84	Cummins	424	85	9/7/82
	A3	4,497,795	2/5/85	Cummins	424	85.6	12/13/82
	A4	5,019,382	5/28/91	Cummins	424	85.4	1/17/90
	A5	5,093,338	3/3/92	Byrne	514	291	4/23/91
	A6	5,624,895	4/29/97	Sobel	514	8	2/18/94
V	A7	5,780,021	7/14/98	Sobel	424	85.4	3/5/93

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
7JS/	B1	WO 94/20122	9/15/94	WIPO			English
/JS/	B2	WO 96/28183	9/19/96	WIPO			English
7JS/	В3	WO 83/03411	10/13/83	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Ref. Des.	Citation
Ċ1	"Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. The IFNB Multiple Sclerosis Study Group," Neurology 43:655-661. 1993.
C2	Bayley et al., "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," J. Pharm. Phramacol. 47(9):721-724. 1995.
C3	Bocci et al., "Is interferon effective after oral administration? The state of the art." J. Biol. Regul. Homeos. Agents, 4(2):81-83, 1990.
C4	Bocci, "Absorption of cytokines via oropharyngeal-associated lymphoid tissues," Clin Pharmacokinet, 21(6):411-417, 1991.
	C1 C2 C3

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EXAMINER:

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DATE CONSIDERED:

03/20/2007

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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/JS/	C5	Bocci, "Immunomodulators as local hormones: new insights regarding their clinical utilization," Journal of Biological Response Modifiers, 4:340-352, 1985.				
	C6	Bosio et al., "Efficacy of low-dose oral use of type I interferon in cytomegalovirus infections in vivo," J. Interferon Cytokine Res., 19:869-876, 1999.				
	C7	Brod and Khan "Oral administration of IFN- α is superior to subcutaneous administration of IFN- α in the suppression of chronic relapsing experimental autoimmune encephalomyelitis," J. Autoimmunity, 9:11-20, 1996.				
	C8	Brod et al., "Ingested (oral) IFN-alpha induces MxA mRNA in RRMS" (Submitted for publication)				
	C9	Brod et al., "Ingested IFN-α has biological effects in humans with relapsing-remitting multiple sclerosis," Mult. Scler., 3:1-7, 1997.				
	C10	Brod et al., "Ingested interferon α suppresses type I diabetes in non-obese diabetic mice," Diabetologia, 41:1227-1232, 1998.				
	C11	Brod et al., "Ingested interferon alpha induces Mx mRNA," Cytokine, 11:1-8, 1999.				
	C12	Brod et al., "Ingested interferon alpha preserves residual best cell function type 1 diabetes," J. Interferon Cytokine Res., 2(12):1021-1030, 2001.				
	C13	Brod, "Hypothesis: multiple sclerosisis a type I interferon deficiency syndrome," Proc. Soc. Exp. Biol. Med. 218:278-283, 1998.				
	C14	Butcher, "The regulation of lymphocyte traffic," Current Topics in Microbiology and Immunology, 128:85-122, 1986.				
	C15	Cantell and Pyhala, "Circulating interferon in rabbits after administration of human interferon by different routes," Virol, 20:97-104, 1973.				
	C16	Carter et al., "Disease modifying therapies in multiple sclerosis," CNS Drugs, 3:99-114, 1995.				
	C17	Connelly, "Interferon beta for multiple sclerosis," Ann. Pharmacother., 28(5):610-616, 1994.				
	C18	Dhingra et al., "A phase-I clinical study of low-dose oral interferon-alpha," J. Immunother., 14(1):51-55, 1993.				
C19		Fleischmann et al., "Orally administered interferons exert their white blood cell suppressive effects via a novel mechanism, Neurology, 13, 1993.				

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/JS/	C20	Gibson et al., "Pharmacokinetics of recombinant leukocyte A interferon following various routes and modes of administration to the dog," Journal of Interferon Research, 5:403-408, 1985.				
١.	C21	Giron et al., "Effect of interferons and poly(I):poly(C) on the pathogenesis of the diabetogenic variant of encephalomyocarditis virus in different mouse strains," J. Interferon Res., .8(6):745-753. 1988.				
	C22	Goldsteein et al., "Human biologic response modification by interferon in the absence of measurable serum concentrations: a comparative trial of subcutaneous and intravenous interferon-β serine," Journal of the National Cancer Institute, 81(14):1061-1068, 1989.				
	C23	Goodkin et al., "Experimental therapies for multiple sclerosis: current status," Cleve. Clin. J. Med., 59:63-74. 1992.				
	C24	Gross et al., "Interferon-α with condylomata acuminata and juvenile diabetes mellitus," Deutsche Medizinische Wochenschrift, 111(36):1351-1355, 1986. (Abstract)				
		Higgins et al., "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin basic protein and its fragments," J. Immunol. 140:440-445, 1988.				
	C26	Horisberger, "MX protein: function and mechanism of action, Biotechnolgy, Ciba-Geigy Ltd., CH-4002 Basel, Switzerland.				
	C27	Hutchison et al., "Chronic recurrent aphthous stomatitis: oral treatment with low-dose interferon alpha," Mol. Biother., 2:160-164, 1990.				
	C28	Koech et al., "Efficacy of Kemron (low dose oral natural human interferon alpha) in the management of HIV-1 infection and acquired immune deficiency syndrome (AIDS)," East Afr. Med. J., 67(7 Supp 2):SS64-70, 1990.				
	C29	Koech et al., "Low dose oral alpha-interferon therapy for patients seropositive for human immunodeficiency virus type-1 (HIV-1)," Mol. Biother., 2(2):91-95. 1990.				
	C30	Konrad et al., Biological Barriers to Protein Delivery, ch. 14, 409-437, ed. Audus et al. 1993.				
	C31	Larocca et al., "Evaluation of neutralizing antibodies in patients treated with recombinant interferon-β ser," Journal of Interferon Research, 9(Supp 1):S51-S60, 1989.				
V	C32	Lecce et al., "Treatment of rotavirus infection in neonate and weanling pigs using natural human interferon alpha," Mol. Biother. 2(4):211-216, 1990.				

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/JS/	C33	Liu et al., "Accumulation of protein O-GlcNAc modification inhibits proteasomes in the brain and coincides with neuronal apoptosis in brain areas with high O-GlcNAc metabolism," J. Neurochem, 89(4):1044-1055.					
	C34	Mashkovskii et al., "Drugs," Moscow, Meditsina, 2:389-392, 1993.					
	C35	Mowat et al., "The regulation of immune responses to dietary protein antigens," Immun. Today, 8:93-98, 1987.					
	C36	Nagler et al., "Immunotherapy with recombinant human interleukin-2 and recombinant interferon-alpha in lymphoma patients postautologous marrow or stem cell transplant," Blood, 89:3951-5959.					
	C37	Owens et al., "The immunology of multiple sclerosis and its animal model, experimental allergic encephalomyelitis," Neurol. Clin, 13(1):51-73, 1995.					
	C38	Paulesu et al., "Oral administration of human recombinant interferon-a2 in rats," Elsevier Science Publishers B.V. (Biomedical Division), 46:199-202, 1988.					
C39		Radwanski et al., "Pharmacokinetics of interferon α-2b in healthy volunteers," J Clin Pharmacol, 27:432-435, 1987.					
	C40	Satoh et al., "Suppression of late asthmatic response by low-dose oral administration of interferon-beta in the guinea pig model of asthma," J. Interferon Cytokine Res., 19:887-894, 1999.					
	C41	Schafer et al., "Interferon administered orally: protection of neonatal mice from lethal virus challenge," Science, 176:1326-1327, 1972.					
	C42	Shibutani et al., "Toxicity studies of human fibroblast interferon beta (I) acute and subacute toxicity studies in mice and rats," <i>Iyakuhin Kenkyu</i> , 18:571-582. (1987) (Abstract)					
	C43	Shim et al., "Administration route dependent bioavailability of interferon-α and effect of bile salts on the nasal absorption," Drug Dev. Indus. Pharm., 19:1183-1199. 1993.					
	C44	Thompson et al., "Gastric administration of type II collagen delays the onset and severity of collagen-induced arthritis in rats," Clin. Exp. Immunol., 64(3):581-586, 1985.					
V	C45	Vial et al., "Clinical toxicity of the interferons," Drug Saf., 10(2):115-150, 1994.					
_₹	C46	Wedner et al., Basic Clinical Immunology, 7th edition Chap 34, 1991					

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/JS/	C47	Wills et al., "Pharmacokinetics of recombinant alpha A interferon following IV infusion and bolus, IM, and PO administration to African green monkeys," Journal of Interferon Research, 4(3):399-409, 1984.	
	C48	Witt et al., "Absence of biological effects of orally administered interferon-βser," Journal of Interferon Research, 12:411-413, 1992.	
$\sqrt{}$	C49	Yershov et al., "Interferon status in different diseases," Voprosy Virusologii, 35:444-448, 1990 (Russian)	

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